DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 3, 2014

ZOLL Circulation, Inc.
Ms. Susan Noriega
Director of Regulatory Affairs
2000 Ringwood Avenue
San Jose, California 95131

Re: K141139
Trade/Device Name: Solex Intravascular Heat Exchange Catheter
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: NCX
Dated: September 2, 2014
Received: September 4, 2014

Dear Ms. Susan Noriega,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141139

Device Name
Solex Intravascular Heat Exchange Catheter

Indications for Use *(Describe)*

The Solex Intravascular Heat Exchange Catheter connected to the CoolGuard 3000/Thermogard XP Thermal Regulation System is indicated for use:

In cardiac surgery patients to achieve and/or maintain normothermia during surgery and recovery/intensive care, and to induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care.

Maximum use period: 48 hours.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

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PREMARKET NOTIFICATION 510(K) SUMMARY

Date Prepared:	April 23, 2014
Submitter:	ZOLL Circulation, Inc.
Address:	2000 Ringwood Avenue San Jose, CA 95131
Phone:	408-541-2140
Fax:	408-541-1030
Contact Person:	Susan Noriega, Director Regulatory Affairs
Trade Name/Proprietary Name:	Solex® Intravascular Heat Exchange Catheter
Common Name:	Central Venous Catheter (short term) and Thermal Regulating System
Classification/Name:	Class II; System, Hypothermia, Intravenous, Cooling
Regulation:	21 CFR 870.5900, Thermal Regulatory System
Product Code:	NCX
Legally marketed devices to which substantial equivalence is claimed:	ZOLL Solex Catheter, Kit Model 510(k) K081936 ZOLL Cool Line Catheter Kit Model CL-2295A, Icy Catheter Kit Model IC-3893A, Quattro Catheter Kit Model IC-4593 510(k) K101987

I. Device Description:

The ZOLL Solex Intravascular Heat Exchange Catheter (Solex Catheter) is a sterile, single use 9.3F flexible catheter designed for placement in the superior vena cava from an insertion site in the jugular vein. The Solex Catheter is connected to a single use, disposable CoolGard 3000® or Thermogard XP® Start-Up Kit (SUK) and the CoolGard 3000® or Thermogard XP® Console, all of which comprise the ZOLL Intravascular Heat Exchange System. The Start-Up Kit (SUK) and the CoolGard 3000 or Thermogard XP Console are supplied separately. The ZOLL Heat Exchange System is also designed for use with an off-the-shelf temperature probe. The Solex Catheter is comprised of a polyurethane shaft and a serpentine shaped PET balloon at the distal end. The blood contact surfaces of the catheter incorporate a hydrophilic heparin coating as an anti-thrombogenic agent.

The catheter has five lumens, two of which when connected to the Start-Up Kit, are used to circulate sterile saline in a closed loop circuit for heat exchange with the blood in the central venous system. Heated or chilled saline is pumped through the heat exchange lumens, inflating the diameter of the PET balloon that interfaces with the patient's blood system to warm or cool circulating blood. The inflow/outflow lumens form a closed-loop system through which the heated or chilled saline circulates. The heated or chilled saline is not infused into the patient. Additional lumens of the Solex Catheter consist of a 0.032" guidewire compatible lumen that can also be used as a primary infusion lumen, and two additional infusion lumens within the catheter shaft.

II. Indications for Use:
The intended use / indications for use of the modified Solex Catheter is identical to that of the 510(k) cleared Solex Catheter (K081936).

The Solex® Intravascular Heat Exchange Catheter connected to the CoolGard 3000®/Thermogard XP® Thermal Regulation System, is indicated for use:

- In cardiac surgery patients to achieve and or maintain normothermia during surgery and recovery/intensive care, and
- To induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care.

Maximum use period: 48 hours

III. Technological Characteristics of the Device Compared to the Predicate Device:
The modified Solex Catheter is substantially equivalent to the 510(k) cleared Solex Catheter (K081936), as well as the other cleared ZOLL Catheters (K101987), with regard to intended use / indications for use, technological characteristics, and principles of operation. **Table 1** provides a comparison of the similarities and differences in technological characteristics between the modified Solex Catheter, the cleared Solex Catheter, and other cleared ZOLL Catheters (Cool Line, ICY and Quattro).

Table 1. Comparison of Proposed Solex Catheter with Predicates

Feature	ZOLL Intravascular Heat Exchange Catheters		
	SUBJECT DEVICE Modified Solex Catheter with SurModics Applause Heparin Coating	**PREDICATE DEVICE Solex Catheter with Edwards LifeSciences DuraFlo Heparin Coating**	**ADDITIONAL PREDICATE DEVICES Cool Line, ICY and Quattro Catheters**
510(k) Number	TBD	K081936	K101987
Device	Solex Intravascular Heat Exchange Catheter - Model SL-2593	Solex Intravascular Heat Exchange Catheter - Model SL-2593	Cool Line Catheter Kit- Model CL-2295A, Icy Catheter Kit - Model IC-3893A, Quattro Catheter Kit - Model IC-4593
Indications for Use	The Solex Catheter connected to the CoolGard 3000/Thermogard XP Thermal Regulation System is indicated for use: • In cardiac surgery patients to achieve and/or maintain normothermia during surgery and recovery/intensive care, and • To induce, maintain and reverse mild	The Solex Catheter connected to the CoolGard 3000/Thermogard XP Thermal Regulation System is indicated for use: • In cardiac surgery patients to achieve and/or maintain normothermia during surgery and recovery/intensive care, and • To induce, maintain and reverse mild	The Quattro Catheter and ICY Catheter connected to a ZOLL Thermal Regulation System are indicated for use: • In cardiac surgery adult patients to achieve and/or maintain normothermia during surgery and recovery/intensive care, and • To induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care.

Feature	ZOLL Intravascular Heat Exchange Catheters		
	SUBJECT DEVICE Modified Solex Catheter with SurModics Applause Heparin Coating	**PREDICATE DEVICE Solex Catheter with Edwards LifeSciences DuraFlo Heparin Coating**	**ADDITIONAL PREDICATE DEVICES Cool Line, ICY and Quattro Catheters**
	hypothermia in neurosurgery patients in surgery and recovery/intensive care. Maximum use period: 48 hours.	hypothermia in neurosurgery patients in surgery and recovery/intensive care. Maximum use period: 48 hours.	The Cool Line Catheter when used with the ZOLL Thermal Regulation System is indicated for use in fever reduction, as an adjunct to antipyretic therapy, in adult patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated.**
Heparin Coating	SurModics Applause Heparin Coating	Edwards LifeSciences Duraflo Heparin Coating	SurModics Applause Heparin Coating
Max. Use Period	2 days	2 days	7 days – Cool Line 4 days – ICY 4 days – Quattro
Number of lumens	5 lumens: 2 infusion 1 guidewire (also infusion) 1 inflow 1 outflow	5 lumens: 2 infusion 1 guidewire (also infusion) 1 inflow 1 outflow	5 lumens: 2 infusion 1 guidewire (also infusion) 1 inflow 1 outflow
Catheter working length (maximum)	26cm	26cm	22 cm – Cool Line 39 cm – ICY 48 cm – Quattro
Heat exchange balloons	1 (serpentine)	1 (serpentine)	2 (straight/coaxial) Cool Line 3 (straight/coaxial) ICY 4 (straight/coaxial) Quattro
Cross Sectional Area (approx. inflated outer diameter)	$54mm^2$ (12.2 mm OD)	$54mm^2$ (12.2 mm OD)	Cool Line: $20mm^2$ (5 mm) ICY / Quattro: $50mm^2$ (8 mm)
Shaft diameter	9.3 Fr	9.3 Fr	9.3 Fr
Insertion Site	Jugular Vein	Jugular Vein	Quattro – Femoral Vein ICY – Femoral Vein Cool Line – Femoral, Jugular, Subclavian Veins
Materials	Shaft: Polyurethane Heat Exchange Balloon: PET	Shaft: Polyurethane Heat Exchange Balloon: PET	Shaft: Polyurethane Heat Exchange Balloon: PET/ Polyurethane

Feature	ZOLL Intravascular Heat Exchange Catheters		
	SUBJECT DEVICE Modified Solex Catheter with SurModics Applause Heparin Coating	**PREDICATE DEVICE Solex Catheter with Edwards LifeSciences DuraFlo Heparin Coating**	**ADDITIONAL PREDICATE DEVICES Cool Line, ICY and Quattro Catheters**
Sterilization method and SAL	EO, SAL 10^{-6}	EO, SAL 10^{-6}	EO, SAL 10^{-6}

** The Indication for Use for the Cool Line Catheter also includes the following warning:

Warning – Fever Reduction
The safety of this device has not been demonstrated for fever reduction in patients presenting with subarachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarachnoid hemorrhage).

Mortality by Diagnosis (ITT analysis)

	Cool Line			Control			
	n	N	%	n	N	%	p*
CI	3	16	18.8	3	14	21.4	0.74
ICH	8	33	24.2	7	27	25.9	1.00
PTBI	10	44	22.7	4	38	10.5	0.24
SAH	13	61	21.3	7	63	11.1	0.15

*Fischer's exact test

For more details on the clinical trial results please refer to Physician's Manual – "Normothermia for the Neuro-critically Ill stroke patient" #101416-001.

IV. Summary of the Nonclinical Tests Performed:

Nonclinical testing was performed to ensure that the modified ZOLL Solex Catheter meets its predetermined design and performance specifications and that the product is substantially equivalent to the predicate devices (K081936 and K101987).

The modified Solex Catheter is identical to the 510(k) cleared Solex Catheter in terms of intended use/indications for use and principles of operation, and has equivalent technological characteristics. Minor design modifications have been incorporated into the catheter design to improve manufacturability of the device. Nonclinical testing completed includes Bench Performance, Biocompatibility, and Shelf Life Testing to support the labeled expiration date. The non-clinical test results demonstrate that the modified Solex Catheter continues to meet product design specifications.

Bench Performance

Bench performance testing of the modified Solex Catheter was performed to verify that product design specifications were met at T=0 and after real time aging to support the labeled expiration date. Testing completed includes the following: catheter visual inspection, dimensional measurements, life testing, flow rate and pressure monitoring, heat exchange testing, air/liquid leakage testing, burst testing, flex and fatigue testing, and tensile strength testing. Where applicable, testing was performed in accordance with the catheter performance requirements of

ISO 10555-1:2013. The results of the design verification testing demonstrate that the modified Solex Catheter meets its design performance specifications at T=0 and at its labeled expiration date.

Biocompatibility

The modified Solex Catheter is fabricated with similar materials and components as the predicate Solex Catheter and other cleared ZOLL Catheters. In addition, the Solex Catheter utilizes the identical SurModics Heparin Coating as the predicate ZOLL Cool Line, ICY and Quattro Catheters 510(k) cleared in K101987, using the same material substrates. According to ISO 10993-1:2009, *Biological Evaluation of Medical Devices – Part 1: Guidance on Selection of Tests*, the Solex Catheter is categorized as an "external communicating, blood contact device with prolonged exposure (>24 hours to 30 days)". Based on this categorization, the Solex Catheter was tested for Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Subacute Toxicity, Genotoxicity, Implantation, and Hemocompatibility. The results of the testing demonstrate that the Solex Catheter is biocompatible for its intended use.

V. Summary of Clinical Tests Performed:

Clinical evaluations were not performed for the modified Solex Catheter and were not necessary to demonstrate substantial equivalence of the modified Solex Catheter to the predicate devices (K081936 and K101987).

VI. Substantial Equivalence:

The modified Solex Catheter has the same intended use / indications for use as the 510(k) cleared Solex Catheter (K081936). The modified Solex Catheter utilizes the identical SurModics Applause Heparin Coating as other currently cleared ZOLL Catheters (Cool Line, ICY and Quattro - K101987) and has similar technological characteristics as the currently cleared Solex Catheter. The results of the bench performance, biocompatibility and shelf life testing demonstrate that the modifications do not affect the performance or function of the device. The minor differences in the design between the modified and cleared Solex Catheters, as well as other ZOLL predicate Catheters, do not raise any new types of safety or effectiveness questions as confirmed by design verification testing. Therefore, the modified Solex Catheter is substantially equivalent to the previously cleared predicate devices.

VII. Conclusions:

ZOLL concludes that based on the results of the bench performance, biocompatibility and shelf life testing, that the Solex Catheter is substantially equivalent to the predicate devices.